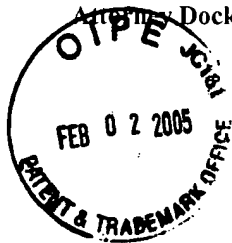


02-03-05

Ifn

Patent Docket No.: LXGN-00104

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: **PERSON**
Serial No.: **09/933,528**
Filing Date: **August 20, 2001**
Examiner: **Brusca, John S.**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service via Express Mail with sufficient postage in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date indicated below:

2/1/05
Date

Michelle Kuhn
Michelle Kuhn

Title: **Region Definition Procedure and Creation of a Repeat Sequence File**

Mail Stop Amendment
Commissioner of Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Enclosed are the following:

1. Copy of Notice of Non-Compliant Amendment dated January 14, 2005
2. Copy of Office Action dated July 23, 2004;
3. Corrected Response to Office Action dated July 23, 2004; and
4. Acknowledgement Postcard.

McDaniel & Associates, P.C. hereby authorizes the Commissioner to charge any fees necessary to McDaniel & Associates P.C. Deposit Account No. 50-1085 for the filing of these documents.

Respectfully submitted,



Date: 201.05

C. Steven McDaniel
Registration No. 33,962
ATTORNEY FOR APPLICANT

McDaniel & Associates, P.C.
P.O. Box 2244
Austin, Texas 78768-2244
Phone: 512.472.8282
Fax: 512.472.8181



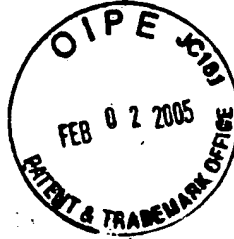
UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,528	08/20/2001	Christophe Person	LXGN-00104	8324

7590 01/14/2005

C. Steven McDaniel, Esq.
McDaniel & Associates, P.C.
P.O. Box 2244
Austin, TX 78768-2244



EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

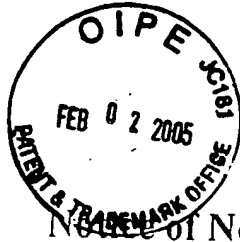
DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

69/933,528
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 2023
www.uspto.gov



Paper No.

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 12-21-01 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see 68 Fed. Reg. 38611, Jun. 30, 2003). In order for the amendment document to be compliant, correction of the following omission(s) or provision is required. Only the section (1.121(h)) of the amendment document containing the omission or non-compliant provision must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.

THE FOLLOWING CHECKED (X) ELEMENTS(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____
- ☐ 3. Amendments to the drawings: _____
- ☒ 4. Amendments to the claims:
 - ☒ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all claims (incl. withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified.
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given **ONE MONTH** from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this **ONE MONTH** time limit is **not extendable**.

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION**, and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a **TIME PERIOD** of **ONE MONTH** from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

Legal Instruments Examiner (LIE)

July 22, 2003 (rev.)

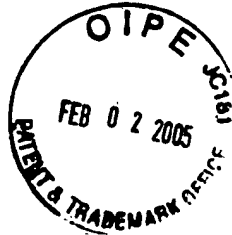


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,528	08/20/2001	Christophe Person	LXGN-00104	8324

7590 07/23/2004
C. Steven McDaniel, Esq.
McDaniel & Associates, P.C.
P.O. Box 2244
Austin, TX 78768-2244



EXAMINER

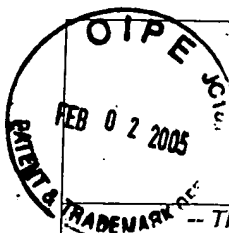
BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.

09/933,528

Applicant(s)

PERSON, CHRISTOPHE

Examiner

John S. Brusca

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-33 and 39 is/are pending in the application.
4a) Of the above claim(s) 39 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 2,3 and 5-33 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

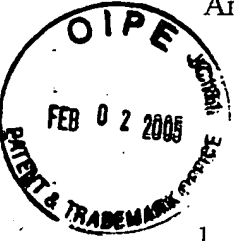
Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/8/02.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____



DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 2 in the reply filed on 16 June 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 39 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 June 2004. In the restriction requirement mailed claim 39 was omitted from nonelected Group 5, drawn to databases. Claim 39 is withdrawn in view of the election of Group 2.
3. It is noted that the response filed 16 June 2004 contains a marked up copy of the claims as required by 37 CFR 1.121 and in addition contains an unnecessary unmarked copy of the claims that will not be considered to be the official copy of the claims.

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or

continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

It is apparent from the rule 63 Declaration filed on 11 December 2001 that the applicants intended to claim the benefit of U.S. Provisional Application No. 60/227099. However until the specification is amended to refer to the above application no claim for benefit will be recognized.

Specification

5. The sequence listing and computer readable form filed 17 March 2003 have been entered into the application history.

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the following reasons:

Several nucleotide sequences appear in the specification in figure 3 that are not properly identified. Nucleotide sequences must be identified by sequence identification number. Furthermore, if said sequences do not appear in the sequence listing, a new listing including said sequences must be supplied. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02). If said sequences consist of a portion of sequences already of record in the sequence listing, they may be identified in the specification using the existing SEQ ID No. accompanied by the position of the sequence on the already listed sequence.

Applicants are required to comply with all the requirements of 37 CFR §§ 1.821-1.825. Any response to this Office Action which fails to meet all of these requirements will be

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considered non-responsive. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The subject matter of claims 10-15 and 17 do not have antecedent basis in the specification.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17 is drawn to methods that use a database encoded in a biological medium. The specification does not describe databases encoded in a biological medium.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 5-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-16 are indefinite for recitation of the phrase "said sequences" because it is not clear which of the sequences in the claims from which claims 5-16 depend the phrase refers to.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 2, 3, 5, 7, 8, 18-20, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurka et al. (1996).

The claims are drawn to a method of making a repeat sequence database by masking repeat sequences in a query sequence wherein the repeat sequences are in a repeat sequence database, and determining if any remaining unmatched sequences in the query sequence are repeat sequences in a repeat sequence database, and if such repeat sequences are determined in the query sequence, the query repeat sequences so determined are added to a repeat sequence database. In some embodiments the right and left endpoints of the match are determined, the sequences are DNA sequences, the sequences are human sequences, the repeat sequence

databases are internet accessible and on computer-readable media, and the matching of sequences are performed by a database search algorithm. In some embodiments the search algorithm is a Smith Waterman algorithm.

Jurka et al. (1996) shows in the program description on pages 119-121 a database matching program called CENSOR. CENSOR determines whether a query sequence contains repeats that match sequences in a repeat sequence database. CENSOR censors those repeat sequences so that the remaining query sequence may be matched against the database of choice without giving undesirable matches to repeat sequences that have been censored. Jurka et al. (1996) shows on page 119 that in the art the terms censor and masking are equivalent. Jurka et al. shows matching of query sequences that are DNA and determination of the right and left endpoints of the match and masked regions in figure 1. Jurka et al. (1996) shows human repetitive databases in the introduction on page 119. Jurka et al. (1996) shows computer-based repeat sequence databases throughout, and use of LOCAL, a Smith Waterman database search algorithm throughout. Jurka et al. shows on page 121 that one use of CENSOR is to allow for masking of repeated sequence followed by a second matching to a repeat sequence database using different parameters for possible identification and censoring of more distant repeats. Jurka et al. (1996) does not show addition of repeats identified by comparison of a masked query sequence to a repeat sequence database.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Jurka et al. (1996) by addition of newly determined repeat sequences to a repeat sequence database so that the repeat sequence database would be a more comprehensive listing of repeat sequences.

15. Claims 2, 6, 15, 16, 19-24, 26-29, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above, and further in view of Altschul et al.

The claims are drawn to the method of claim 2 further limited to analysis of ribonucleotide sequences, sequences that encode amino acid sequences, synthetic DNA such as cDNA, repeat sequence databases accessible through the internet, use of public domain databases GenBank, dbEST, and SwissProt, use of search algorithms BLAST and FASTA, and use of scoring matrices PAM and BLOSUM.

Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above does not show the method of claim 2 further limited to analysis of ribonucleotide sequences, sequences that encode amino acid sequences, repeat sequence databases accessible through the internet, use of public domain databases GenBank, dbEST, and SwissProt, use of search algorithms BLAST and FASTA, and use of scoring matrices PAM and BLOSUM.

Altschul et al. reviews searching sequence databases. Altschul et al. shows searching query sequences derived from mRNA such as cDNA that encode proteins on page 119 and figures 2 and 3. Altschul et al. shows repeat sequence databases accessible through the internet used to mask query sequences on page 128. Altschul et al. shows public domain databases GenBank on page 124, SwissProt on page 127, and dbEST on page 128 (reference 60). Altschul et al. shows use of BLAST and FASTA search algorithms on page 120 and use of scoring matrices PAM and BLOSUM on pages 123-124.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8,

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18-20, 27, and 30 above by use of analysis of ribonucleotide sequences, sequences that encode amino acid sequences, repeat sequence databases accessible through the internet, use of public domain databases GenBank, dbEST, and SwissProt, use of search algorithms BLAST and FASTA, and use of scoring matrices PAM and BLOSUM because Altschul et al. shows use of all of those features in the context of searching sequence databases with query sequences whose repeat sequences have been masked.

16. Claims 2, and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above, and further in view of Jurka (1998).

The claims are drawn to the method of claim 2 utilizing sequences from mice, plants, fungi, and microorganisms.

Jurka (1998) reviews repeat sequences from a variety of organisms. Jurka (1998) points to mouse repeat sequences on page 334 and table 1.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above by use of repeat sequences from a variety of organisms so that corresponding query sequences from the organisms could be analyzed and masked.

17. Claims 2, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above, and further in view of Sohocki et al.

The claims are drawn to the method of claim 2 further limited to use of a TIGR database.

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Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above does not show use of a TIGR database.

Sohocki et al. shows in the abstract and throughout use of the TIGR Human Gene Index database to search for genes for inherited retinal disorders.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Jurka et al. (1996) as applied to claims 2, 3, 5, 7, 8, 18-20, 27, and 30 above by use of the TIGR Human Gene Index database because Sohocki et al. shows that the database is a useful source of human genes such as genes related to inherited retinal disorders.

Conclusion

18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.
19. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (571) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Brusca 21 July 2004
John S. Brusca
Primary Examiner
Art Unit 1631

jsb